AD_____

GRANT NUMBER DAMD17-94-J-4450

TITLE: Biological Specimen Bank to Enhance Population Based Studies of Inherited Breast Cancer Genes

PRINCIPAL INVESTIGATOR: Frederick P. Li, M.D.

CONTRACTING ORGANIZATION: Dana-Farber Cancer Institute
Boston, Massachusetts 02115-6084

REPORT DATE: October 1997

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 1997	Annual (30 Sep 96 - 29 Sep 97)

4. TITLE AND SUBTITLE
Biological Specimen Bank to Enhance Population Based Studies of Inherited Breast Cancer Genes

5. FUNDING NUMBERS
DAMD17-94-J-4450

6. AUTHOR(S)
Frederick P. Li, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Dana-Farber Cancer Institute
Boston, Massachusetts 02115-6084

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200*

The objectives of this infrastructure enhancement project are to establish a population-based biological specimen and companion risk-factor data bank on 225 invasive breast cancer cases, aged 35 and under. These breast cancer cases have been enrolled through the tumor incidence registries in Connecticut, Massachusetts and 7 regions in California with a total population of 21 million (8% of US women). Demographic, epidemiologic and family history data have been collected on 225 cancer cases, and fresh blood specimens have been processed to produce a lymphoblastoid cell line, cDNA and plasma in years 1-3. Presently, at the end of year 3 of the 4-year study, a computerized file of the epidemiologic data and specimen data has been generated. Despite a series of initial obstacles, we have completed on schedule all activities outlined in our Statement of Work. As planned for year 4, we have announced the availability of the resource to researchers via Internet. An Outside Advisory Committee will prioritize requests for tissues and risk factor data. This new resource will be available to multiple investigators for detection of p53, BRCA1/2 and other inherited breast cancer susceptibility genes, and studies of gene-environmental interactions.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Breast Cancer, Familial Cancers, Population-based Registries, Breast Cancer Genes, Germline mutations	22
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

____ Where copyrighted material is quoted, permission has been obtained to use such material.

____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

DL For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

NA In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

NA In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

PI - Signature 10/3/97 Date

Table of Contents

INTRODUCTION

Our purpose was to develop a biological specimen bank and epidemiological database of 225 early onset invasive breast cancer cases (ages 35 and under) enrolled in the population-based cancer incidence registry in Connecticut, Massachusetts and 7 regions of California (Santa Clara region, Central Valley, Sacramento, Inland Empire, San Diego, Bay Area, and Orange regions). Approximately one-third of breast cancer cases under age 35 are carriers of an inherited gene: estimated carrier rates are 36% at ages 20-29; 29% at age 30; 28% age 31; and 24% at 35 years. The cut-off at age 35 is based on sample-size considerations. This resource will provide an infrastructure for the identification and studies of inherited breast cancer susceptibility genes, and their interactions with hormonal and environmental risk factors. The cases will be generated from a population base of 21 million (8% of entire US population) that is of special interest to breast cancer researchers. Age-adjusted cancer mortality rates, 1985-89, in Massachusetts ranks 6th highest nationwide, and Connecticut ranks 13th [1, 2]. Both States are in the high breast cancer-mortality belt that spans the Middle Atlantic and New England regions. California, the most populous state in the nation, has substantial minority populations, including Asian-Americans (9.9%), Hispanic-Americans (20.9%), and Black-Americans (6.1%) in the study regions. The racial composition of Massachusetts is 88% Whites, 5% Hispanics, 5% Blacks, 2% Asians, and 0.6% others. In Connecticut, there are 83% Whites, 8% Blacks, 7% Hispanics and 2% Asians and 0.1% others

BODY

The objectives of the proposal are to identify all incident invasive breast cancer cases, ages 35 and under in a 3-year period, using rapid ascertainment systems available for the population covered by the cancer incidence registries of the State of Connecticut, Commonwealth of Massachusetts, and 7 regions in California that encompass 8% of the entire US population. With permission of the treating physician and patient, we planned to collect a completed questionnaire for 225 subjects, as well as peripheral blood. We proposed to use the blood sample to establish a lymphoblastoid line, produce cDNA, a plasma specimen, and store viably frozen cells along with paraffin blocks in laboratories of the PI and co-PIs in California and Massachusetts. At the end of year 3, we would make available to approved investigators all questionnaire and specimen summary data. An Outside Advisory Committee of leading scientists will be prioritize requests from any breast cancer investigator for biologic specimens.

Methods were defined to uniformly collect blood specimens and questionnaire data from incident invasive breast cancer cases (age 35 and under) ascertained in Years 1-3 through the population-based cancer registries for Massachusetts and Connecticut, and 7 participating regions of California. Processing of specimens and establishment of a tissue repository and epidemiologic database for at least 225 cases would be completed by year 4. At year 4, the announcement of the database will be kept on-line for e-mail accession, and specimens will be distributed worldwide to investigators with high priority studies. Despite initial obstacles, we are on schedule and the project will be completed as described and later modified with DOD approval.

We had established mechanisms for rapid case ascertainment of all incident breast cancer cases within the initial 24 months of the project; obtaining informed consent from subjects; administering a standardized interview; performing a phlebotomy and processing the specimen [3-10]. Rapid case ascertainment systems differ slightly in California, Massachusetts and Connecticut. The approach in each region has been determined by cost considerations, and established resources.

In California, the project was conducted through the Cancer Surveillance Program for all 7 population-based California cancer registry regions [3-5]. In addition to the fact that cancer reporting is mandatory throughout the State of California, the Cancer Surveillance Program has long maintained a close working relationship with health care facilities and physicians through the region. Many hospitals participate in joint cooperative clinical research protocols. The Cancer Surveillance Program also circulates a newsletter which is used to inform local healthcare facilities and physicians of the study and ensure prompt enrollment of all patients. The rapid case ascertainment systems previously developed for this region have been used in all 7 population-based California cancer registry regions. The Cancer Surveillance Program staff contacted all health care facilities in the region that diagnose breast cancer cases. The Cancer Committee Chair and Tumor Registrar of each hospital of these regions were informed of the study. One individual from each facility was designated as the contact person with the Cancer Surveillance

Program staff for rapid identification. The Cancer Surveillance Program staff worked with them to examine pathology reports and surgery logs on a regular basis.

In Connecticut, the rapid case ascertainment system has been used for many studies over the last decade [6]. For this project, rapid case ascertainment was used to identify cases in the 9 hospitals found in a preliminary study to have reported two-thirds of the incident early-onset breast cancers. Other patients were identified through the usual reporting mechanisms of reporting cancer incidence to the Connecticut Tumor Registry.

In Massachusetts, pilot data show that the majority of very young breast cancer cases are referred to a few specialty centers for consultation and treatment. These cases can be efficiently ascertained at lowest cost by directly approaching clinicians and hospital tumor registries of the Dana-Farber Cancer Institute (the Regional Comprehensive Cancer Center), its sister institutions in Harvard Medical School (Brigham and Womens, Massachusetts General, Beth Israel, Deaconess, and Mount Auburn Hospitals), and Dana-Farber Affiliate community hospitals. Nearly 2/3 of all incident breast cancers of early onset in Massachusetts can be rapidly ascertained through these institutions. The remaining 1/3 of all cases will be contacted after they are reported to the Massachusetts Tumor Registry [7].

Recruitment of subjects, informed consent and Questionnaire administration for California cases were handled through UC Irvine, and Massachusetts and Connecticut cases were through Dana-Farber. Consent to participate in this study is a 2-step process. Initially, the physician of the subject was contacted for permission to inform the patient of the study and request voluntary participation. With physician consent, the patient was sent a letter that explained the study, and subsequently telephoned. After a signed consent was obtained a telephone questionnaire was administered. In addition, arrangements were made for collection of up to 50 ml of peripheral blood by venipuncture at a facility specified by the patient.

Arrangements were made for collection and shipment of blood specimens to Boston. We have extensive experience in collecting, shipping and processing freshly collected blood samples from study subjects within the United States [3-5, 8-11]. Cases either came to Dana-Farber, UC Irvine or Yale for phlebotomy or blood was drawn by their family doctor, oncologist or local health care facility. The physician or clinic designated by the patient was contacted, and the purpose and procedures explained. A package with consent form, blood collection and handling instructions, Leukoprep tubes, and a pre-paid shipping invoice was sent prior to the date of collection. No medical complications were encountered. These specimens were delivered to the laboratory in Boston by express mail (or by taxi for specimens collected locally). Cells were used to generate EBV immortalized lymphoblastoid cells. This process involves culturing cells over a period of 6-8 weeks before stable immortalized cells are established. A test of cell-viability was performed before the immortalized cells are considered properly frozen and stored. Requests from researchers for a cell line can either be filled directly from these frozen vials or by thawing out samples and regenerating more frozen sample vials. If available, primary lymphocytes have also been viably frozen in 10% DMSO as a reserve source of cells in case there is ever a need to regenerate a new lymphoblastoid cell line, as well as produce genomic DNA.

During the study, however, we had to modify our proposal regarding collection of breast tumor blocks. Hospitals are refusing to send us the blocks, a departure from past standard of practice. Alternatively, they were willing to cut slides, but often at charges of over $100. A supplemental request to our award could not be made and the Project Officer agreed to drop this aspect of the project. We have met all other study objectives within the time specified in our proposal. To ensure equal access to the resources, requests will be prioritized by the Outside Advisory Committee. The following breast cancer researchers have agreed in writing to serve on the Committee:

Dr. Bruce Ponder, Director, CRC Human Cancer Genetics Research Group, Cambridge University, England;

Dr. Barbara Weber, Director, Breast Oncology Program, University of Michigan Medical and Genome Center; and

Dr. Anne Bowcock, University of Texas, Southwestern Medical Center.

A group of leading epidemiologists, clinical investigators, molecular biologists and geneticists have been contacted regarding their personal use of the resource to be developed under this proposal. Availability of the database and specimens is being announced on the Internet.

CONCLUSIONS

All aspects of our study have been completed on time. Specifically, we have collected risk factor data from 225 patients under age 36, as stated in our Statement of Work. We have collected bloods from each of these 225 patients. Lymphoblastoid cell lines have been successfully established when adequate volume of blood has been obtained. We have already placed an announcement on the Internet regarding the availability of the specimen resource. Our External Advisory Committee is prepared to review our request for utilization of the materials and data. The work has been accomplished despite multiple early problems with hospital IRBs who questioned various aspects of the DOD requirements for informed consent. Since this is an infrastructure grant, no publications were expected or produced.

REFERENCES

1. Boring CC, Squires TS, Tong T. Cancer Statistics. Cancer 1993;43:7-26.

2. Miller BA, Gloeckler LA, Hankey BF, Kosary CL, Edwards BK. U.S. Department of Health and Human Services. Cancer Statistics Review 1973-1989 ;NIH publication No. 92-2789.

3. Anton-Culver H. Epidemiologic assessment of cancer risk: Application from the cancer surveillance program of Orange County. Journal of the American College of Toxicology 1989;8:933-940.

4. Anton-Culver H, Bloss JD, Bringman D, Lee-Feldstein A, DiSaia P, Manetta A. Comparison of adenocarcinoma and squamous cell carcinoma of the uterine cervix: A population-based epidemiologic study. American Journal of Obstetrics and Gynecology 1992;166:1507-1514.

5. Seiffert JE, Price WT, Gordon B. The California tumor registry: A state-of-the-art model for a regionalized automated, population-based registry. Topics in Health Record Management 1990;11(2):59-73.

6. Cusano MM, Young JLJ. Forty-five years of cancer incidence in Connecticut: 1935-1979. U.S. Department of Health and Human Services, vol NIH Publication No 86-2652).

7. Friedman DJ, Gershman ST. Cancer Incidence in Massachusetts 1982-1988. .

8. Li FP. Cancer families: human models of susceptibility to neoplasia - The Richard and Hilda Rosenthal Foundation Award Lecture. Cancer Research 1988;48:5381-5386.

9. Li FP, Fraumeni JF, Jr., Mulvihill JJ, Blattner WA, Dreyfus MG, Tucker MA, Miller RW. A cancer family syndrome in twenty-four kindreds. Cancer Research 1988;48:5358-5362.

10. Garber JE, Goldstein AM, Kantor AF. Follow-up study of twenty-four families with Li-Fraumeni syndrome. Cancer Research 1991;51:6094-6097.

11. Malkin D, Jolly KW, Barbier N, et al. Germline mutations of the p53 tumor suppressor gene in children and young adults with second malignant neoplasms. New England Journal of Medicine 1992;326(20):1309-1315.

APPENDIX A

PRELIMINARY SUMMARY OF QUESTIONNAIRE RESULTS

DEMOGRAPHIC INFORMATION										
EDUCATION	TOTAL	<8 YEARS	8-11 YEARS	12 YEARS	SOME COLLEGE	COLLEGE GRAD	MASTERS	MD, PHD, JD	OTHER	
	261	0	8	52	82	79	14	3	23	
%	100	0.0	3.1	19.9	31.4	30.3	5.4	1.1	8.8	
MARITAL		SINGLE	MARRIED	SEPARATED	DIVORCED	WIDOWED	LIVING AS MARRIED			
	261	45	181	5	19	0	11			
%	100	17.2	69.3	1.9	7.3	0.0	4.2			
RELIGION		BAPTIST	EPISCOPOLIAN	JEWISH	METHODIST	MORMAN	PRESBYTERIAN	PROTESTANT	CATHOLIC	UNITARIAN	OTHER
	251	12	10	8	11	1	5	28	126	1	49
%	100	4.8	4.0	3.2	4.4	0.4	2.0	11.2	50.2	0.4	19.5
ETHNIC		WHITE	BLACK	HISPANIC	ASIAN	NATIVE AMERICAN	OTHER				
	261	204	13	28	3	1	12				
%	100	78.2	5.0	10.7	1.1	0.4	4.6				
SPOUSE EDU		<8 YEARS	8-11 YEARS	12 YEARS	SOME COLLEGE	COLLEGE GRAD	MASTERS	MD, PHD, JD	OTHER		
	213	2	5	81	53	41	10	8	13		
%	100	0.9	2.3	38.0	24.9	19.2	4.7	3.8	6.1		

PREGNANCY AND FERTILITY													
		No	Yes										
EVER PREG		71	190										
		0	1	2	3	4	5	6	7				
TOTAL TIMES PREG	190		35	73	45	19	14	2	2				
LIVE PREG	326		54	86	23	5	1	1	0				
MISCAR	69		32	13	2	0	1	0	0				
STILL BIRTH	3		3	0	0	0	0	0	0				
ABORTION	94		37	21	2	1	1	0	0				
Out Come			Live	Still birth	Miscar	Abort	Multiple	Preg now					
PREG 1	190		115	0	26	47	2	0					
PREG 2	166		106	3	22	23	1	0					
PREG 3	82		57	1	8	13	2	1					
PREG 4	37		26	0	6	5	0	0					
PREG 5	17		8	0	1	6	1	1					
PREG 6	2		1	0	0	0	1	0					
	483	0	313	4	63	94	7	2					
							Early+		full term+	late +			
Duration of Pregnancy		don't know	<8	8-15	16-23	24-31	32-35	36-39	40-43	44-47		don't know	
PREG WKS 1		1	32	33	2	2	3	32	77	4		5	
PREG WKS 2		3	16	25	2	3	10	33	63	1		2	
PREG WKS 3		0	5	15	1	2	5	16	34	2		1	
PREG WKS 4		1	4	4	0	1	1	7	18	0		2	
PREG WKS 5		0	1	4	0	0	0	2	7	0		2	
PREG WKS 6		0	0	0	0	0	0	0	1	0		1	
Live born			Boy	Girl	Twin Girls	Twin Boys	Twin boy & girl						
BIRTH 1	117		63	52	1	0	1						
BIRTH 2	107		50	56	0	1	0						
BIRTH 3	69		29	28	0	2	0						
BIRTH 4	26		13	13	0	0	0						
BIRTH 5	9		5	3	1	0	0						
BIRTH 6	2		1	0	0	1	0						
	320												
Birth Weight Oz.		<80	80-88	89-96	97-104	105-112	113-120	121-128	129-136	137-144	145-152	153-160	>160
OZ 1		2	5	4	10	19	12	27	12	11	8	4	3
OZ 2		3	2	3	6	15	20	18	24	11	6	4	1
OZ 3		1	0	8	2	9	10	12	12	5	4	0	0
OZ 4		0	0	0	2	1	9	6	4	3	2	0	0
OZ 5		0	0	1	1	2	1	0	0	3	0	0	1
OZ 6		0	0	0	0	1	0	0	0	0	0	0	1
Birth Weight Oz.		<88	89-104	105-120	121-136	137-152	>152						
OZ 1		7	14	31	39	19	10						
OZ 2		5	9	35	42	17	6						
OZ 3		1	10	19	24	9	0						
OZ 4		0	2	10	10	5	0						
OZ 5		0	2	3	0	3	2						
OZ 6		0	0	1	0	0	2						
		No	Yes										
BRFEED 1	117	43	74										
BRFEED 2	107	39	68										
BRFEED 3	59	26	33										
BRFEED 4	26	11	15										
BRFEED 5	9	4	5										
BRFEED 6	2	1	1										
Weeks breast fed		1 to 9	10 to 19	20 to 29	30 to 39	40 to 49	50 to 59	60 to 69	70 to 139				
NURSE 1		20	16	11	11	5	8	0	3				
NURSE 2		14	21	12	7	2	3	5	4				
NURSE 3		7	7	6	6	3	1	3	0				
NURSE 4		4	5	2	1	0	1	1	1				
NURSE 5		2	1	2	0	0	0	0	0				
NURSE 6		1	0	0	0	0	0	0	0				
		48	50	33	25	10	13	9	11				
		No	Yes										
PREG MED		179	11										
Birth No.			1	2	3	4	5	6					

MED PREG 1	7		4	2	1	0	0	0					
MED PREG 2	4		2	1	1	0	0	0					
MED PREG 3	2		0	0	1	1	0	0					
Medication taken to hold preg			Other	Pills	Shots	Yutapar	brethine & MGH	Macadansen	Progesterone				
PMED 1	7		0	2	2	1	0	1	1				
PMED 2	4		0	1	2	0	1	0	0				
PMED 3	2		0	0	1	0	1	0	0				
			<10	10to19	20to29	30to39							
ST PMED WKS 1			3	0	2	2							
ST PMED WKS 2			2	0	2	0							
ST PMED WKS 3			0	0	1	1							
Weeks taken During pregnancy			<10	10to19	20to29	30to39	Don't know						
PMED WKS 1			4	2	0	1	0						
PMED WKS 2			2	0	0	1	1						
PMED WKS 3			1	0	0	0	1						
		No	Yes										
TRY PREG	260	227	33										
FERT TEST	34	21	13										
Problem due to:			Self	Husband	Both	None				know			
FERT PROB	13		4	2	2	3				2			
		No	Yes										
FERT DRUG	261	255	6										
Birth Control Pills													
		No	Yes										
BCP	261	31	230										
Months taken	Don't know	<1	1 to 11	12 to 23	24 to 35	36 to 47	48 to 59	60 to 71	72 to 83	84 to 95	96 to 107	108 to 119	>=120
BCP MOS 1	7	1	45	34	28	23	19	20	6	6	8	8	25
BCP MOS 2	5	0	28	34	26	15	10	6	3	2	4	2	5
BCP MOS 3	14	0	14	6	7	7	5	1	0	2	2	1	1
Reason not used BCP			Yes										
BCP Dr.			2										
BCP FAMHX			1										
BCP SAFE			6										
BCP CHOICE			23										
		No	Yes										
OTH HORM USE	261	231	30										
HORM NAME													
HORM REASON													
HORM ST													
	Months		0 to 11	12 to 23	24 to 35	36 to 47	>100						
HORM MOS	30		20	5	1	2	2						

Health

		No	Yes	<10	10to14	15to19	20to24	25to29	30to35	
GALL BLADDER	261	245	16							
AGE GALL				0	0	0	4	6	6	
ACNE	261	241	20							
AGE ACNE				0	10	4	2	2	2	
DIABETES	261	257	4							
AGE DIABETES				0	1	0	0	2	1	
POLYPS	261	259	2							
AGE POLYPS				0	1	0	0	0	1	
HIRSUTISM	261	251	10							
AGE HIRSUT				0	1	3	1	1	1	
OV CYST	261	209	52							
AGE CYST				1	1	10	4	15	18	
HBP	261	253	8							
AGE HBP				0	0	2	2	2	2	
HI CHOL	261	234	27							
AGE CHOL				0	0	2	6	6	11	
PELVIC SURG	261	243	18							
				1	0	6	2	5	4	
EST		17	1							
FIBROCYSTIC	261	207	54							
AGE FIBRO				0	0	9	12	22	10	
PRIOR BX	261	232	29							
REASON BX			28	0	1					
PRIOR BX AGE				0	1	8	6	4	8	
			Benign Cyst	Malignancy	Unkn					
BX FIND			26	2	1					
BR SURG	261	249	12							
BR SIZE		3	9							
BR SURG AGE				0	0	2	3	6	1	
			Augmentation	Reduction	Other					
BR PROCED			8	2	2					
			Self	Mamogam	MD	Other				
BR FOUND	261		208	17	22	14				
SMOKING HISTORY										
		No	Yes							
SMOKE 100		153	108							
SMOKE NOW		74	34							
		0	1 to 9	10 to 14	15 to 19	20 to 24	25 to 29	30 to 34		
SMOKE START			1	25	67	14	1	1		
SMOKE END			0	0	9	27	27	12		
DUR_SMOKE years		2	22	24	27	13	1	0		
		1 to 4	5 to 9	10 to 19	20 to 29	30 to 39	40 to 49	50 to 59	60 to 69	Don't Know
CIG DAY		24	13	32	27	3	4	0	1	4

HEIGHT, WEIGHT & ACTIVITY																
		9	10	11	12	13	14	15	16	17	18	19	20 to 24	25to 29	30+	dk
MEN 1ST		8	12	40	74	69	35	12	6	2						3
MEN REG AGE		2	10	20	46	36	39	25	19	9	15	4	9	0	3	15
			Natural	BC Pills	Other	Never reg										
MEN REG			210	40	2	9										
			Much lower	Some what	Averag e	some what	much higher									
HEIGHT 12			18	38	100	57	48									
WEIGHT 12			43	59	114	39	6									
		no	yes													
VIG PHY 12		110	151		104 to	156 to	208 to	260 to	312 to	364 to						
times per year			<52	52 to 103	155	207	259	311	363	415						
VIG FREQ 12			1	4	18	31	13	42	5	35						
Req to keep wt low?		no	yes													
VIG WEIGHT 12		148	3													
MOD PHY 12		24	237		104 to	156 to	208 to	260 to	312 to	364 to						
times per year			<52	52 to 103	155	207	259	311	363	415						
MOD FREQ 12			1	12	30	47	16	55	1	69						
Req to keep wt low?		no	yes													
MOD WEIGHT 12		235	2													
			very slender	average	a little over weight	very over weight					Don't know					
BUILD 20			90	115	50	5					1					

Height	Inches	<60	60	61	62	63	64	65	66	67	68	69	>69	dont know				
HEIGHT 20		7	14	13	24	26	36	32	28	24	22	12	23	0				
WEIGHT	pounds	<90	90-99	100 to 109	110 to 119	120 to 129	130 to 139	140 to 149	150 to 159	160 to 169	170 to 179	180 to 189	190 to 199	200+	dont know			
WEIGHT 20		1	11	35	43	69	39	23	11	8	8	4	0	5	4			
		no	yes															
VIG PHY 20		174	87		104 to	156 to	208 to	260 to	312 to	364 to								
times per year			<52	52 to 103	155	207	259	311	363	415								
VIG FREQ 20			5	6	8	19	15	16	5	11								
		no	yes															
VIG WEIGHT 20		80	4															
MOD PHY 20		75	186															
			<52	52 to 103	104 to 155	156 to 207	208 to 259	260 to 311	312 to 363	364 to 415								
MOD FREQ 20			8	14	42	49	23	24	1	23								
		no	yes															
MOD WEIGHT 20		182	4								0							
		<100	100 to 109	110 to 119	120 to 129	130 to 139	140 to 149	150 to 159	160 to 169	170+								
WEIGHT LO		16	42	58	62	36	14	13	10	6								
WEIGHT HI		0	6	16	30	50	33	31	25	61								
		<20	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
WEIGHT LO AGE			94	38	19	20	14	22	10	8	8	6	10	3	2	2	0	0
WEIGHT HI AGE		10	10	8	4	5	12	20	12	11	16	17	32	13	17	30	27	12
		Never over weight	below waist	around above waist	equal													
WEIGHT GAIN	261	4	142	46	69													

Alcohol									
		No	Yes						
ALCOH 16	261	169	92						
BEER 16	92	18	74						
WINE 16	92	65	27						
LIQ 16	92	58	34						
			1 to 5	6to10	11to15	15to20	20+	Dont know	
BEER WK 16	74		46	19	3	0	1	5	
WINE WEEK 16	27		25	2	0	0	0	0	
LIQ WK 16	34		25	2	3	1	3	0	
		No	Yes						
ALCOH 20	261	101	160						
BEER 20	160	56	104						
WINE 20	104	95	63						
LIQ 20	62	83	78						
			1 to 5	6to10	11to15	15to20	20+	Dont know	
BEER WK 20	104		58	32	10	3	1	0	
WINE WK 20	62		56	5	1	0	0	0	
LIQ WK 20	76		59	9	3	5	0	0	

PRENATAL INFORMATION								
		No	Yes	Dont know				
MO DES	258	218	6	34				
MO DIABETES	258	245	2	11				
MO DIAB PREV	2	2	0	0				
PREM1 were you premature	258	245	13					
		dont know	<70	70to89	90to109	110to129	130to149	150to169
BIRTH WGT		63	6	13	41	98	29	8
		No	Yes	Dont know				
TWIN PREG	258	252	6					
B DEFECT	258	227	29	2				
B PROBLEM								
MO BRFEED	258	159	73	26				
			<3mths	3-9mths	>9mths	Don't Know		
MO NURSE	73		12	24	13	24		
		No	Yes					
MO SMOKE	258	170	78			10		
FA SMOKE	258	93	151			14		
SMOKE HOME	258	76	179			3		
OCCUPATION								
JOB	261	1	260					
OCCUP		<16	16 to20	21to25	26to 30	>30		
OCCUP_AGE		14	115	104	24	3		
		no	yes					
OCCUP RAD	261	243	18					
		<16	16 to20	21to25	26to 30	>30		
OCCUP RAD AGE	17	0	10	4	3	0		
		no	yes					
ELECTRIC	261	169	92					
		<10	10to19	20to29	30+			
ELECTRIC AGE		9	37	42	4			

APPENDIX B

RESOURCE ON NIH WEBSITE

NATIONAL CANCER INSTITUTE

NATIONAL ACTION PLAN ON BREAST CANCER
A Public/Private Partnership

Breast Cancer Specimen/Data Resource

Name:

Dana Farber Cancer Institute

Address:

44 Binney Street
Boston, MA 02115

Description:

The Dana Farber Cancer Institute has established a population-based biological specimen and risk factor data bank on 225 invasive breast cancer cases, who were aged 34 and under. One-third of these exceptionally young study subjects are estimated by statistical analysis to be carriers of a susceptibility gene. These 225 women have been ascertained over 3 years through the tumor incidence registries in Connecticut, Massachusetts, and 7 regions in California, with a total population of 21 million (8% of U.S. women). This work was supported by the U.S. Army Medical Research and Material Command under DAMD-17-94-J-4450.

CONTACT INFORMATION

Type(s) of Specimens Available:

Fresh blood specimens have been processed to produce:

- a lymphoblastoid cell line
- genomic DNA
- plasma
- viably frozen cells.

Number of Specimens Held:

225 cell lines and frozen blood specimens

Other Available Data:

- **Demographic:** Age, sex, race, ethnicity
- **Clinical:** Laterality (right, left, both breasts)
- **Other:** Age at diagnosis, medical history, family history, pregnancy and fertility, smoking, alcohol, prenatal

NOTE: All questionnaire data at this stage are unconfirmed.

Researcher Requirements for Obtaining Specimens/Data:

Breast cancer-related specimens/data are available or procured for distribution to outside researchers without restrictions related to collaboration. An outside advisory committee will prioritize requests for specimens and risk factor data. All specimens sent to outside investigators will remain stripped of identifiers.

Procedures to Obtain Access to Specimens/Data:

Contact Dr. Frederick Li or Katie Nicholls for further information.

Costs to Researchers:

Approved researchers will be required to pay for the costs associated with generating and delivering all specimens, such as cell lines.

Limitations of Specimen Use:

No information that identifies an individual subject will be provided.

Consent:

Not applicable. Data provided will be non-identified.

Date of Last Update:

July 31, 1997

Parent document within information database hierarchy *[Returns user to first screen.]*

Breast Cancer Specimen/Data Resource/ September 17, 1997 □